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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/609,233	CHAUDRY, IMTIAZ	
	Examiner	Art Unit	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04/27/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,12-16,21,25-30,32,34,38-40,51-54,57-64 and 66-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 12-16, 21, 25-30, 32, 34, 38-40, 51-54, 57-64 and 66-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 04/27/09. Claims 1, 2, 27, 38 and 51 have been amended, no claims have been cancelled or newly added. Accordingly, claims **1, 2, 12-16, 21, 25-30, 32, 34, 38-40, 51-54, 57-64 and 66-71** remain pending.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

NOTE: The claim set filed on 04/27/09 has the claim identifier of (New) for claims 70 and 71. The said claims were added by way of an amendment filed on 10/06/08. The incorrect claim identifiers should be corrected in the next claim set.

Claim Rejections - 35 USC § 112

Claims **1, 2, 12-16, 21, 25-30, 32, 34, 38-40, 51-54, 57-64 and 66-71** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims 1, 27, 38 and 51 include the added

recitation of "reduced level of the hypertension reducing agent is absorbed into the systemic blood circulation and systemic effects are reduced". Specification does not provide support for the said recitation. Sections 0011, 0012 and 0036 of the published document, contrary to what Applicant claims, do not provide support for the said recitation. Section 0036, reproduced below, does not recite, for example, any level of active agent in the blood circulation. Also, "systemic effects" is not disclosed, only side effects are said to be decreased.

[0036] The present invention is premised, in part, on the known systemic hypertension reducing effects of ACEIs, ARBs, beta-blockers, calcium-channel blockers or vasodilators to treat pulmonary hypertension. It is believed that the formulations of the present invention represent an improvement over conventional means for treating pulmonary hypertension, because the delivery of the hypertension-reducing agent would be localized to the user's pulmonary system, as opposed to systemic delivery. It is believed that localized therapy may increase bioavailability as well as increased efficacy and/or prolonged therapeutic effect. Due to increased bioavailability, the present formulations may contain lower dosages of the hypertension-reducing agents while effectively treating pulmonary hypertension. Additionally, it is believed that localized therapy may result in a decrease in side-effects due to lower dosages and a decrease in patient discomfort and inconvenience due to the less invasive or time-consuming systemic delivery method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 12-16, 21, 25-30, 32, 34, 38-40, 51-54, 57-64, 66-69 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (5,554,610), as evidenced by Newman (Aerosol deposition considerations in inhalation therapy, CHEST, 1985, in view of Schwarz (US 20010031738) and further in view of Mead et al (6,608,054).

Williams teaches a **method for the treatment** of **pulmonary hypertension** comprising administering to a mammal an effective amount of a vasodilator. The formulations can treat primary and secondary pulmonary hypertensions (col. 2, lines 1-6). The administration is preferably **through inhalation**. **Unit doses** comprising 0.01 to 50 mg. The usual daily dose is in the range of 0.0001 to 1 mg/kg/day, thus the daily dose for a 70 kg adult would be 0.01 to 50mg. The compositions are prepared by admixture and can be in a solution or **suspension** form (col. 2, lines 16-48, 60-67). One preferred composition comprises in an **aqueous suspension** form, additives such as suspending agents, preservatives, carriers and **buffers**. The said agents include **propylene glycol**, **ethyl alcohol,** etc. The compositions for administration to the respiratory tract are presented as snuff or an **aerosol** or **solution** for a **nebulizer** or as a microfine powder for insufflation, alone or in combination with an inert carrier. In other preparations, such as for parenteral administration, the fluid unit dose forms are

prepared containing the compound and a **sterile** vehicle, undergo **filter sterilization** and filled into a vial. The compositions are typically accompanied by written or printed directions for use (see col. 3, lines 1-66).

Williams also discloses that suitable vasodilators include **calcium channel blockers** such as **nifedipine** (col. 4, lines 20-21). A particularly favored pharmaceutically acceptable composition is an inhalation composition, suitably in unit dosage form (col. 4, lines 37-40). Williams lacks disclosure on pH levels, isotonicity of the formulations and addition of complexing agents.

Newman teaches that inhalation therapy has several well-established advantages over the oral and intravenous routes; 1) **A small dose of drug** can be used, a few hundred micrograms of inhaled beta-agonist may be as effective as a 10-mg oral dose. 2) There is a rapid onset of action. 3) There is a **low incidence of systemic** side effects (see page 152s, 1st col.).

Schwarz teaches a method of treating **pulmonary hypertension by inhalation**. It is disclosed that the aerosol **suspensions** can be aerosolized by a metered dose inhaler ([0049]) or with a pressure-driven **aerosol nebulizer** or an **ultrasonic nebulizer**. The suitable carrier is typically water and most preferably **sterile** water, and preferably made **isotonic**. Optional preservatives, **pH-adjusting agents**, **buffering** agents and **surfactants** are included. Such agents include sodium citrate, sodium gluconate, sodium lactate, etc (see [0041] and [0051]). The doses of the active

compounds may be provided as **one or several prepackaged units** (see [0059]). It is disclosed that suitable formulations comprise **citrate** or bis/tri buffer (**pH 6**) (see [0045]). Suitable emulsifying agents include lecithin ([0044]).

Schwarz discloses that "Regardless of the route of administration of the active compounds or formulations of the invention, the therapeutically effective dosage of any one active compound, the use of which is in the scope of present invention, will vary somewhat from compound to compound, and patient to patient, and will depend upon factors such as the age, weight and condition of the patient, and the route of delivery. Such dosages can be determined in accordance with routine pharmacological procedures known to those skilled in the art. For example, as a general proposition, a dosage from about 0.1 to about 50 mg/kg will have therapeutic efficacy, with all weights being calculated based upon the weight of the active compound" (see [0056]).

Mead et al teach pharmaceutical compositions based on anticholinergics and endothelin antagonists, processes for preparing them and their use in the treatment of respiratory tract disease (see abstract). The said disorders include **pulmonary hypertension** (see col. 2, lines 56-64). Mead discloses that the formulation preferably have a **pH of from 2 to 7**, which is obtained by addition of acids or a mixture of acids. Preferably acids which have other properties in addition to their acidifying qualities, e.g. complexing agent, antioxidant, etc. The addition of editic acid (EDTA) or one of the known salts thereof, sodium edentate, as stabilizer or complexing agents is unnecessary. Other embodiments may contain this compound or these compounds. In

a preferred embodiment the content based on sodium edetate is less than 100mg/100ml. Generally, inhalable solutions in which the content of **sodium edetate** is from 0 to 10mg/ml are preferred (col. 9, lines 1-35). Preferred formulations contain, in addition to the solvent water and the combination of active substances, only benzalkonium chloride and sodium edetate (col. 10, lines 8-11). The formulations also comprise excipients such as preservatives, buffering agents and surfactants. Suitable surfactants include soya lecithin (col. 9, lines 50-61). Examples B1 and B2 in column 15 disclose formulations comprising **0.3% lecithin.**

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented teachings of Schwarz on inhalation of formulation for treating pulmonary hypertension, with the general teachings and formulations of Williams et al and the formulations of Mead et al with a reasonable expectations of successfully preparing efficient and easy to use formulations that treat pulmonary hypertension in patients. In other words Williams et al are teaching the inhalation of vasodilators for treating pulmonary hypertension. Williams et al disclose the use of buffers for their formulations, however, they are silent with regards to specific pH levels and isotonicity of the formulations. It is well known in the art that mucosal membranes tolerate certain isotonicity and pH levels. It is also well known in the art that pH levels are adjustable by use of acids, bases or buffers. Schwarz have been provided as supportive art showing that it is known in the art that an isotonic formulation having pH levels of 3-8 are suitable for inhalation. Mead et al is also supportive art showing that

adding complexing agents to formulations are known. Thus it is clearly shown that all limitations of the instant claims are met by Williams in view of Schwarz and Mead et al or knowledge generally available to one of ordinary skill in the art. In summary, **all** the claimed elements were known in the prior art and one skilled in the art **could have** combined the elements as claimed by known methods with no change in their respective functions, and the **combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

With regard to the specific concentration range of the claims, it is considered that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). See MPEP 2144.05.

This rejection is also based on the well established proposition of patent law that **no invention resides in combining old ingredients** of known properties where the

results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al (5,554,610) as evidenced by Newman, in view of Schwarz (US 20010031738), Mead et al (6,608,054) and in further view of Illum (5,804,212).

Williams et al, Schwarz and Mead et al are discussed above. The combination of the references lack disclosure on addition of alginates to the formulations. This deficiency is cured by Illum.

Illum teaches spray formulations comprising active agents and excipients (enhancing agents). Suitable excipients include lecithin, EDTA and alginates. Active agents include nifedipine.

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the combined teachings of references to have looked in the art for other and specific enhancing agents such as alginates and lecithin as taught by Illum with reasonable expectation of successfully preparing a stable and effective formulations for treating pulmonary hypertension. In other words, the claims would have been obvious because the **substitution** of one known element for another would have

yielded predictable results to one of ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1, 2, 12-16, 21, 25-30, 32, 38-40, 51-54, 57-71** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-7, 10-14, 16, 21 and 25-26 of copending Application No. 11/316,458 (US 20060104913). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are anticipated by the reference claims. The instant claim 1 and the reference claim 1 both recite an inhalable formulation for the treatment of pulmonary hypertension comprising from 0.1 to 15 mg/ml of a reducing agent such as calcium channel blocker wherein the formulation is free of a compound selected from the group consisting essentially of I) an anti-EMAP II antibody, ii) antisense EMAP II oligonucleotide and iii) EMAP II antagonist and wherein the formulations have a pH of from 3 to 8. The difference is that instant claim 1 contains a further negative proviso wherein the formulation is not a liposome. The remaining claims are also anticipated by the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed 04/27/09 have been fully considered but they are not persuasive.

Applicant argues that the references, individually or in combination do not teach or suggest or render predictable all currently claimed elements. Applicant states that " In particular, each of the cited references, alone or in any combination, fail to teach, suggest, or render predictable any of the following: (1) a formulation adapted for localized delivery to the lungs having a reduced concentration of a calcium channel blocker comprising about 0.001 to about 0.50 mg/ml; (2) a formulation adapted for localized delivery to the lungs such that a reduced level of the hypertension reducing agent is absorbed into the systemic blood circulation and systemic effects are reduced" (Remarks, page 10).

This is not persuasive because Williams et al is clearly teaching delivery of active agents such as calcium channel blockers to the lungs by inhalation for the treatment of pulmonary hypertension. Inhalation to the lung IS localized delivery. Thus active agents are delivered by inhalation to the respiratory system, the lung. Williams et al discloses a daily dosage of from 0.001mg to 1 mg/kg/day. The frequency is disclosed as once or up to 3 times a day. Assuming a normal person weighing about 70kg, the daily dose is from 0.0070 mg to 0.021 mg/day. One of ordinary skill in the art also knows that inhalation delivery requires a much lower dose that oral as shown by Newman. Thus it is assumed that since Williams et al teach both oral and inhalation methods of delivery, that the lower doses are for inhalation.

With regards to Applicant's 2nd comment, 1) It is noted that Applicant has not shown that they have support for the claimed recitation. 2) Williams et al teach the same medicament being delivered to the same site by the same method at the same dose.

Thus, it is considered that the same reduced level of systemic absorption would occur through the method described by the reference. Applicant has merely argued that the teachings of Williams et al are different or that they do not teach a localized delivery or that they do not teach the same concentration range, without any evidence or showing as to how the Williams et al's reference is different.

Applicant also recites that "Williams is generally directed to methods of treating disorders associated with pulmonary hypertension by administering a given dose (mg) of a vasodilator, ganglion blocker, sympathetic nerve blocker or calcium channel blocker. Williams teaches that a "unit dose will normally contain 0.01 to 50 mg for example 0.01 to 10 mg, of the Compound, or a pharmaceutically acceptable salt thereof. Unit doses will normally be administered once or more than once a day, for example 2, 3, or 4 times a day, more usually 1 to 3 times a day such that the total daily dose is normally in the range of 0.0001 to 1 mg/kg." Applicant then argues that "The lowest dosage range disclosed in Williams is 4 orders of magnitude lower than that of the highest dosage. Due to the breadth of such a teaching, Williams fails to provide any particular teaching that would provide the skilled artisan a reasonable basis for specifically selecting and preparing a formulation having the currently claimed concentration range from the nearly infinite possibilities referenced by Williams. For instance, when taken in 0.0001 increments (since this is the lower limit of Williams range), there are 10,000 different concentration levels for one skilled in the art to select. Williams provides no teaching that would incite one skilled in the art to select any particular concentration range" (see Remarks, pages 10-11).

This above arguments are not persuasive. 1) The fact that the lowest dose is 4 orders of magnitude lower than the higher dose is not a teaching away or reason for un-obviousness. As mentioned above, Williams is disclosing the dosage range for all the disclosed methods of delivery including oral and inhalation. Thus one of ordinary skill in the art, especially in light of Newman's disclosure, would expect the range to be broad. Furthermore, Applicant's own specification disclose that acceptable concentration range is from 0.001 to 20 mg/ml, all for inhalation delivery (see specification, pages 14-16).

With regards to Applicant's argument regarding Williams et al not disclosing concentration range or that the daily dose provides for 10,000 different concentration levels, the argument is not persuasive because Williams et al disclose their formulations for delivery by an inhalation device. One of ordinary skill in the art is more than aware of the restrictions of volume and delivery amount of the device and they would know how to adjust to meet the said restrictions. In other words, one of ordinary skill in the art would be able to determine the proper concentration for the device used with no undue experimentation.

Applicant repeatedly argues that "Williams is silent regarding methods of treating pulmonary hypertension by locally delivering a calcium channel blockers to the lungs". Again, this is not persuasive because in William et al's reference, the title recites "**Inhalational treatment of pulmonary hypertension** and related conditions", the abstract and the specification repeatedly and in detail describe treating pulmonary hypertension by inhalation of calcium channel blockers to the lungs. As stated above, this is "localized delivery". Thus contrary to Applicants assertions, Williams et al is NOT

silent regarding the said methods or compositions and expressly teaches the claimed method and compositions.

Applicants arguments regarding the rejection of claims over Kiechel et al in view of Williams et al and Mead et al are persuasive and have been withdrawn.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Primary Examiner
Art Unit 1616